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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018
26111	7590	05/04/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				LI, RUIXIANG
ART UNIT		PAPER NUMBER		
				1646

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/475,158	GARDELLA ET AL.
Examiner	Art Unit	
Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 March 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 and 14-42 is/are pending in the application.
- 4a) Of the above claim(s) 15-35 and 38-40 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11, 14, 37, 41 and 42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12/30/1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### **Status of Application**

The Request filed on March 2, 2004 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/475,158 is granted. An action on the RCE follows.

### **Applicants' Amendment and Claims**

Applicants' amendment filed on January 2, 2004 has been entered in full. Claims 1 and 10 have been amended. Claims 41 and 42 have been added. Claims 1-11 and 14-42 are pending. Claims 1-11, 14, 37, 41, and 42 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Withdrawn Objection**

The objection to disclosure as set forth in Paper No. 22 (October 2, 2003) has been withdrawn in view of Applicants' argument that the sequences of SEQ ID NOS: 9, 11, and 13 are amidated, whereas those of SEQ ID NOS: 3, 5, and 6 are not.

**Objection to the Disclosure**

(i) The disclosure is objected to because of the following informality: there is apparently a typographic error in line 9 of page 7 of the specification: the word "functional" should be "binding". Appropriate correction is required.

(ii) The abstract of the disclosure is objected to because of the presence of materials on the page of abstract that are not related to the disclosure. Correction is required. See MPEP § 608.01(b).

**Drawings**

The drawings filed on December 30, 1999 are objected for various defects in the drawings (for details, please see form PTO-948 that was attached to the Paper No. 18, November 6, 2002). A notice of requirement for submission of formal drawings was attached to the office action (Paper No. 18, November 6, 2002). The corrected drawings have not been received by the office yet.

**Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope of Enablement)**

The rejection of claims 1-11, 14, and 37 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (Scope Enablement), as set forth in Paper No. 18 and Paper No. 22, is maintained. New claims 41 and 42 are also rejected under 35 U. S. C. § 112, 1<sup>st</sup> paragraph on the same basis.

At the top of page 12 of the amendment filed on January 2, 2004, Applicants argue that Applicants have amended the claim 1 in order to address the Examiner's concerns that

there is no specific functional limitation for the claimed compounds. This is not persuasive because the newly added limitation does not define a specific, meaningful biological function. In addition, claims 7-9 have not amended to address the rejection over the "functional derivatives" recited in claims 7-9.

At the middle of page 12 of the amendment filed on January 2, 2004, Applicants argue that Applicants have amended the claim 1 to overcome the rejection over the issue of the undefined linker. This has been fully considered, but is not deemed to be persuasive because the scope of the linker recited in the amended claim is still too broad: the length of the linker is undefined in claim 1; the type of the linker encompasses any amino acids or any aliphatic diamines. The specification fails to provide sufficient guidance and working examples on how to make and/or use such a broad of genus of linkers and consequently fails to enable an artisan to make and/or use a compound comprising an undefined linker. In this regard, it is noted that, while PG5 shows an induction of cAMP in COS-7 cells expressing human PTH-1receptor, PG9, which has 4 more glycine residues in the linker, has a minimal effect on induction of cAMP (Fig. 3). Therefore, even the length of the linker can dramatically changes the activity of the polypeptide.

**Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Written Description)**

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 7-9 recite “functional derivatives”. The claims do not require that the “functional derivatives” possess any particular conserved structure or disclosed distinguishing feature. However, the instant disclosure of the polypeptides as recited in the claims does not adequately support the scope of the claimed genus. The instant disclosure fails to provide sufficient description information, such as definitive structural features of the claimed genus of polypeptide. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The specification also fails to provide a reasonable number of representative species of the genus. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polypeptide as being identical to those instantly claimed. It is noted that mere assertion of what a compound does without disclosure of the

chemical structure of the compound is not sufficient to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

Due to the breadth of the claim genus and lack of the definitive structural features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

#### **Claim Rejections Under 35 U. S. C. § 112, 2<sup>nd</sup> Paragraph**

Claims 1-11, 14, 37, 41, and 42 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “a biological activity *substantially similar* to PTH(1-34) or PTHrP (1-34)”. Neither specification nor the art define the term “*substantially similar*” unambiguously. In addition, claim 1, part a, recites “an amino terminal signaling functional domain of PTH”, which is not defined in the specification unambiguously. Thus, it is not clear what the metes and bounds of the terms are, rendering the claim indefinite. Claims 2-11, 14, 37, 41, and 42 depend from claim 1, either directly or indirectly.

#### **Claim Rejections under 35 USC § 102 (b)**

(i) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii). Claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Caulfield et al. (Endocrinology, 127: 83-87, 1990).

Caulfield et al. teach a parathyroid hormone (PTH) fragment, PTH (1-34). The binding domain of PTH (1-34) to PTH receptor is located within the amino acid residues 14-34 (see, e.g., Abstract). If n in the formula S-(L)<sub>n</sub>-B is equal to 1, as permitted by the claims, the formula will become S-L-B. If B is PTH (14-34), the binding domain of PTH (1-34), S is PTH (1-12), the amino terminal signaling functional domain of PTH, a compound with the formula S-L-B becomes PTH (1-34) since the amino acid at position 13 of PTH (1-34) can be considered as "L" as a linker molecule. Thus, the reference of Caulfield et al. reads on the limitations of claims 1-3.

## **Conclusion**

No claims are allowed.

## **Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. The fax number for this Group is (703) 872-9306.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Ruixiang Li, Ph.D.  
Examiner  
May 2, 2004